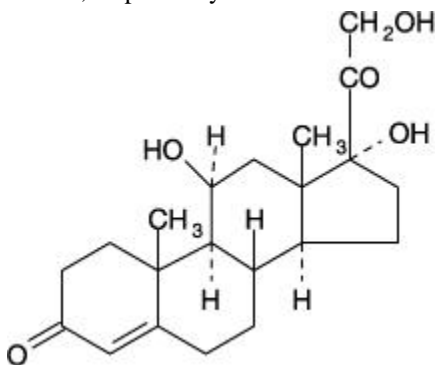


HYDROCORTISONE AND ACETIC ACID - hydrocortisone and acetic acid solution

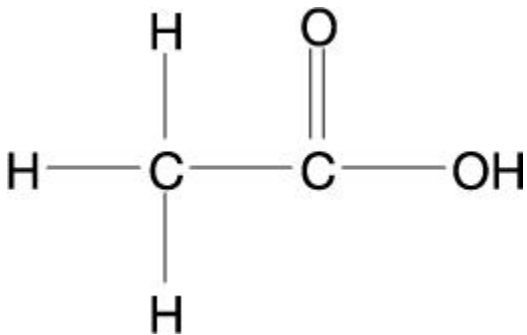
Actavis Inc.

DESCRIPTION

Hydrocortisone and Acetic Acid Otic Solution USP, is a solution containing hydrocortisone (1%) and acetic acid (2%), in a propylene glycol vehicle containing propylene glycol diacetate (3%), benzethonium chloride (0.02%), sodium acetate (0.015%), and citric acid (0.2%). The molecular formulas for acetic acid and hydrocortisone are $C_2H_4O_2$ and $C_{21}H_{30}O_5$, with molecular weights of 60.05 and 362.46, respectively. The structural formulas are:



Chemically, hydrocortisone is: Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-(11 β)-.



This product is available as a nonaqueous otic solution buffered at pH 2 to 4 for use in the external ear canal.

CLINICAL PHARMACOLOGY

Acetic acid is anti-bacterial and anti-fungal; hydrocortisone is anti-inflammatory, anti-allergic and anti-pruritic; propylene glycol is hydrophilic and provides a low surface tension; benzethonium chloride is a surface active agent that promotes contact of the solution with tissues.

INDICATIONS AND USAGE

For the treatment of superficial infections of the external auditory canal caused by organisms susceptible to the action of the antimicrobial, complicated by inflammation.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients, herpes simplex, vaccinia and varicella. Perforated tympanic membrane is considered a contraindication to the use of any medication in the external ear canal.

WARNINGS

Discontinue promptly if sensitization or irritation occurs.

PRECAUTIONS

Transient stinging or burning may be noted occasionally when the solution is first instilled into the acutely inflamed ear.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 3 years have not been established.

ADVERSE REACTIONS

Stinging or burning may be noted occasionally; local irritation has occurred very rarely.

DOSAGE AND ADMINISTRATION

Carefully remove all cerumen and debris to allow solution to contact infected surfaces directly. To promote continuous contact, insert a wick of cotton saturated with the solution into the ear canal; the wick may also be saturated after insertion. Instruct the patient

to keep the wick in for at least 24 hours and to keep it moist by adding 3 to 5 drops of solution every 4 to 6 hours. The wick may be removed after 24 hours but the patient should continue to instill 5 drops of solution 3 or 4 times daily thereafter, for as long as indicated. In pediatric patients, 3 to 4 drops may be sufficient due to the smaller capacity of the ear canal.

HOW SUPPLIED

Hydrocortisone and Acetic Acid Otic Solution USP, 1%/2% is available in a 10 mL measured-drop, safety-tip plastic bottle. Store at controlled room temperature 20°-25°C (68°-77°F).

Keep container tightly closed.

Distributed by:

Actavis Inc.

60 Columbia Rd., Bldg. B

Morristown, NJ 07960 USA

FORM NO. 412

Rev. 4/09

VC3353

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL



